Medical Device Reporting (MDR) User Facilities

Sharon Kapsch
Office of Surveillance and Biometrics
Center for Devices & Radiological Health
Food & Drug Administration

Session Overview

Purpose: To provide information about the Medical Device Reporting (MDR) regulation requirements for User Facilities

Goal: To help you better understand your obligations under the MDR regulation

Authority for Mandatory Reporting: Federal Food, Drug and Cosmetic Act

- Sec 519 - Records and Reports on Devices - grants the FDA authority to require mandatory medical device reports from:
  - (a) Manufacturers and Importers
  - (b) Device User Facilities
- Requirements for MDR are located in 21 CFR Part 803

What is a Medical Device?

An item either used for diagnosis, treatment or prevention of disease, or intended to affect the body, that does not achieve its primary purpose through chemical action or metabolism within the body

*** The FDA definition is in Code 301 Section 201 (h) of FD&C Act.**

Who Must Submit MDRs to the FDA?

Manufacturer

Importer

User Facility

- Hospital
- Ambulatory Surgical Facility
- Outpatient Diagnostic Facility
- Outpatient Treatment Facility
- Nursing Home

Mandatory Requirements for User Facilities

User Facilities are required to:

- Report **deaths** to the FDA and manufacturer
- Report **serious injuries** to manufacturer (or the FDA if manufacturer unknown)
- Submit events within 10 workdays (21 CFR Part 803.30)
- Submit **Annual Reports** to the FDA (21 CFR Part 803.33)
- Have **MDR procedures** (21 CFR Part 803.17)
- Establish and maintain **MDR event files** (21 CFR Part 803.18)

Mandatory Requirements for Manufacturers

Manufacturers are required to:

- Submit **initial reports** of death, serious injury and malfunction within 30 calendar days (21 CFR Part 803.50)
- Submit **5-day reports** within 5 work days (21 CFR Part 803.53)

  Work Day = Monday-Friday, excluding Federal holidays
- Submit **supplemental reports** within 30 calendar days of receipt of new/changed information (21 CFR Part 803.56)
- Have **MDR procedures** (21 CFR Part 803.17)
- Establish and maintain **MDR event files** (21 CFR Part 803.18)

Mandatory Requirements for Importers/Distributors

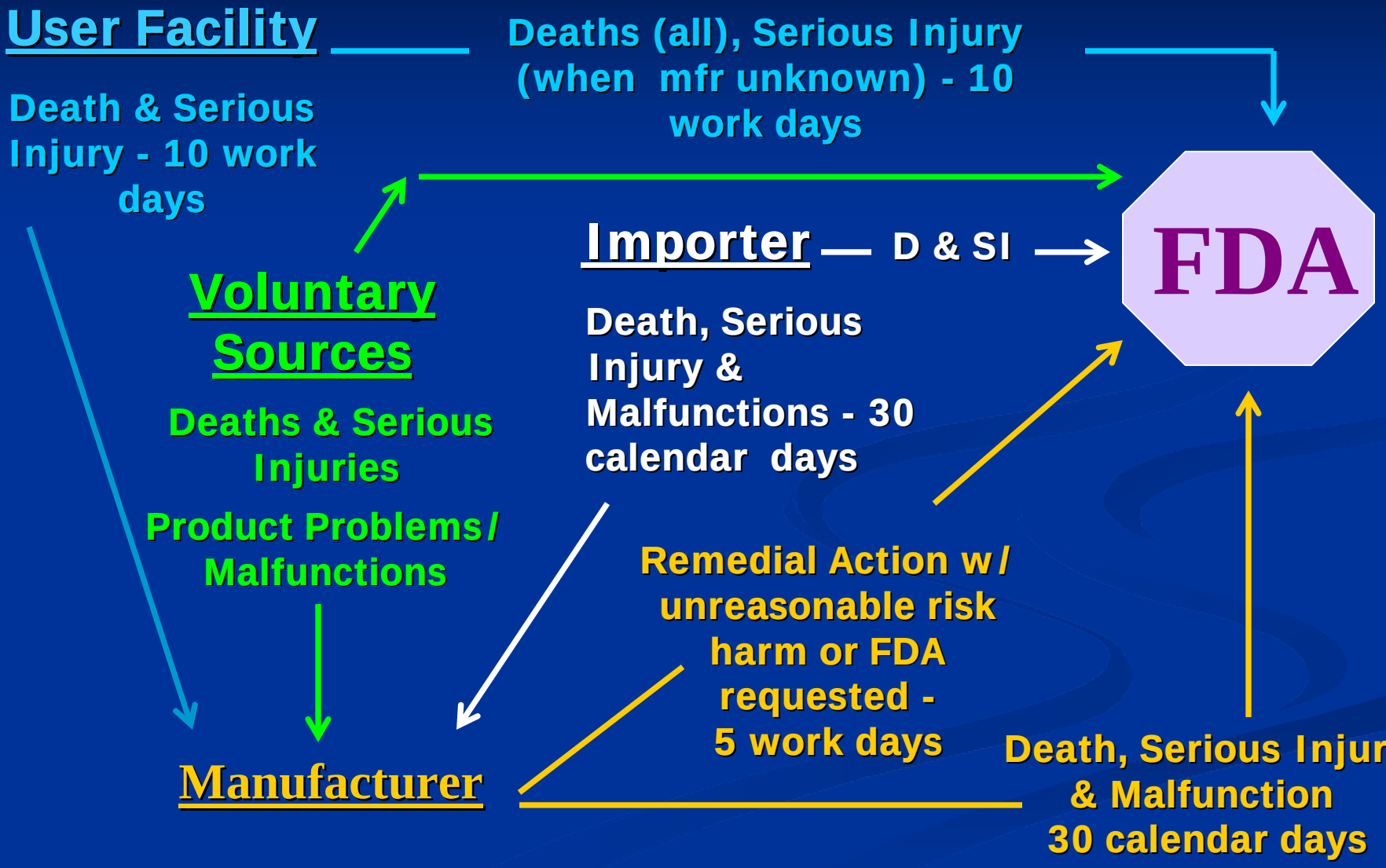
Importers are required to:

- Report **deaths** and **serious injuries** to the FDA and manufacturer
- Report **malfunctions** to the manufacturer
- Submit events within 30 calendar days (21 CFR Part 803.40)
- Have **MDR procedures** (21 CFR 803.17)
- Importers and distributors are required to:
- Establish and maintain **MDR event files** (21 CFR Part 803.18)

Why Does the FDA Need Reports From User Facilities?

- To learn more about how marketed devices perform
- To identify devices that are not safe and effective for their intended use

Data Flow and Reporting Timeframes



How Does the FDA Use Medical Device Reports?

- Event reports are analyzed by FDA staff including health care clinicians, engineers and scientists.
- Follow-up actions that the FDA may be take:
  - Request additional information
  - Conduct an investigation of event
  - Conduct an inspection at the manufacturer, importer or user facility
  - Contact the manufacturer about a recall
  - Issue a public health advisory/safety alert

User Facility Defined

- **Hospital** - performs diagnostic, therapeutic, surgical or other patient services, etc.
- **Ambulatory Surgical Facility** - performs same day outpatient surgical procedures. Examples include surgical, endoscopy or Lasik centers
- **Outpatient Diagnostic Facility** - Conducts medical diagnostic tests, such as a mammography, MRI, or in-vitro testing
- **Outpatient Treatment Facility** - provides nonsurgical therapeutic care on an outpatient basis or in a home setting. Includes ambulance providers, rescue services and home healthcare groups
- **Nursing Home -** provides skilled nursing care, hospice care, or rehabilitative services.

What about a Physician's Office?

A physician's office, whose primary purpose is to only examine, evaluate, and treat or refer patients is not subject to the FDA's reporting requirements

Examples:

- dentist
- chiropractor
- optometrist
- nurse practitioner
- school clinics
- employee health clinics
- freestanding care units

****The FDA encourages physicians to file voluntary reports**

When Does a User Facility "Become Aware" of a Reportable Event?

A User Facility becomes aware when **medical personnel** obtain information that **reasonably suggests** that a device has or may have caused or contributed to the death or serious injury of a patient of the facility

Who is a Patient of the Facility?

- Any individual being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility
- Includes employees of the facility or individuals affiliated with facility, who in the course of their duties suffer a device-related death or serious injury

Who are Medical Personnel?

Any Individual who:

- is licensed, registered or certified to administer health care
- has received a diploma or a degree in a professional or scientific discipline
- is an employee responsible for receiving medical complaints or adverse event reports
- is a supervisor of these persons

What "Reasonably Suggests" an MDR Reportable Event?

Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to a death or serious injury

What is a Serious Injury?

A reportable serious injury is defined as an **Injury** or **Illness** that:

- is life-threatening;
- Results in permanent impairment of a body function or permanent damage to a body structure; or
- Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure

**Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage

What Is “Caused or Contributed”?

MDR defines caused or contributed as:

- a medical device was or may have been a factor in a reportable death or serious injury, or
- a death or serious injury was or may have been attributed to a medical device including events resulting from:
  - Failure
  - Malfunction
  - improper / inadequate design
  - manufacturing (problems)
  - labeling (problems) or
  - user error

When Would You Not Report an Adverse Event?

- Do not report if a person qualified to make a medical judgment (i.e. physicians, nurses, risk managers, and biomedical engineers) has information to reasonably conclude that the device did not cause or contribute to a death or serious injury
- Information to support this decision must be kept in your MDR event files

What is a Malfunction?

- The failure of a device to meet its performance specifications or otherwise perform as intended
  - Performance specifications include all claims made in the labeling for the device
  - Intended performance refers to intended use for which the device is labeled or marketed
- If the malfunction of a device or a similar device is likely to cause or contribute to a reportable death or serious injury if it were to recur, the event is reportable to the FDA
- User Facilities are encouraged to submit Voluntary Reports for malfunctions

How to Submit a Voluntary Report

- Healthcare providers, consumers, and user facilities reporting malfunctions, can use the MedWatch Voluntary Reporting Program
- There are three ways to contact the FDA:
  - Telephone: 1-800-FDA-1088
  - Online report form 3500 (& instructions) accessible at: **http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf**
  - Download or print the form to complete and mail to the address on the form: **http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm**

What Happens to my Report?

- The FDA will send an acknowledgment letter to the reporter
- Reports are entered into the Manufacturer and User Facility Device Experience (MAUDE) database
- Reports (redacted copies) are available on FDAs website at: **www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM**

What Reports Are User Facilities Required to File Under MDR?

- Individual reports submitted in 10 work days using FDA Form 3500A
- Deaths sent to the FDA and manufacturer
- Serious Injuries sent to manufacturers (or the FDA if manufacturer unknown)
- Annual Reports sent to the FDA on January 1 to cover reportable adverse events from prior calendar year

What Information Does the FDA Require from a User Facility?

- A user facility must submit a complete report to the FDA on Form 3500A
- The report must contain all information reasonably known to the user facility about the event
  - This includes information found in documents that are in the possession of the facility and any information that becomes available as a result of a reasonable follow-up within the facility
- A user facility is not required to evaluate or investigate the event by obtaining or evaluating information that it does not reasonably know

When is an MDR Report Not Required?

If a user facility:

- Becomes aware of information from multiple sources on the same patient and the same reportable event (Only one MDR report is required)
- Determines that the information received is erroneous in that a device-related adverse event did not occur.

Document decisions to not report in your MDR file

Address for Mandatory Reporting

FDA/CDRH
Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

Please note the topic on the envelope:

- User Facility Report
- Annual Report

Written MDR Procedures

Importers and Manufacturers must have **Internal systems** that provide for:

- Timely and effective identification, communication, and evaluation of events that may be subject to the MDR requirements
- Standardized review process/procedure for determining when an event meets the criteria for reporting
- Timely transmission of complete device reports

Written MDR Procedures …

Documentation and Recordkeeping requirements for:

- Information evaluated to determine if an event is reportable
- All MDRs and information submitted to manufacturers or the FDA
- Any information evaluated when preparing an annual report
- Systems that ensure access to information that facilitates timely follow up and inspection by the FDA

MDR Event Files

- User Facilities are required to establish and maintain MDR event files
- Files may be written or electronic and may use references to other information/files (i.e. medical records, patient files, etc.)
- Files must contain:
  - Information in your possession or references to information related to the event
  - Documentation of decision making processes used to determine if a death or serious injury was/was not reportable
  - Copies of MDR forms and other information reported to the FDA or the manufacturer

MDR Event Files...

- User facilities must permit FDA to access files, to copy and verify the MDR records
- User facilities must retain MDR event files for 2 years from the date of an adverse event

New Patient and Device Codes for 3500A

The FDA worked with National Cancer Institute (NCI) terminology experts to:

- Reduce duplication and redundancy in current coding
- Create a hierarchy that allows grouping
- Store and maintain the new coding system in the NCI Thesaurus. (Available on the public website/can be downloaded into applications)
- Improve the detection of device safety problems

****Users can request new codes at: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm**

Electronic Medical Device Reporting (eMDR)

- Notice of Proposed Rule Making
  Published August 21, 2009
  Docket Number FDA-2008-N-0393

- Notice of Availability - eMDR Draft Guidance
  Published August 21, 2009
  Docket Number FDA-2008-D-0395

- **eMDR website:**

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/default.htm

Current Regulation

§ 803.12 Where and how do I submit reports and additional information?

(a) You must submit any **written report** or **additional information** required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847–3002.

(Proposed) Final Regulation

§ 803.12 How do I submit reports and supplements?

(a) Manufacturers, user facilities, and importers must submit initial and supplemental reports to FDA in an **electronic format that FDA can process, review, and archive**. FDA will provide and update information on how to provide the electronic submission (e.g., preparation and organization of files, file formats, media and method of transmission)

Final Regulation – Highlights

- Effective one year after publication of final rule
- Keep copies of all submitted reports and acknowledgments
- Reporters may request an exemption from electronic reporting under certain select circumstances
- Housekeeping changes
  - Incorporate § 303 of Medical Device User Fee and Modernization Act of 2002 (Reused Single Use Devices)
  - Change “Date of Report by the Initial Reporter” to “Date of Report”

eSubmitter - Single Reports

- The FDA developed and maintained
- Software free at: **http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm**
- Handles one report at a time
- Captures the data elements required by the FDA Form 3500A
- Validates all data
- Packages the report for the user to send to the FDA Electronic Submissions Gateway

Batch Reporting

- Based on Health Level 7 **(HL7)** Standards Committee Individual Case Safety Report message **(ICSR)**
- Reporter develops software to extract data from reporter's database and prepare the electronic submission
- Capable of handling multiple report submissions at a time
- Minimal human interaction compared to eSubmitter
- Validation of your process is required

Digital Certificates

- You will need a digital certificate to communicate with the FDA gateway
- Minimal cost per certificate renewable each year
- The certificate will cover any electronic submission that uses the FDA gateway such as Registration & Listing
- Information and instructions on setting up an account and communicating with the FDA gateway are available at:

http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

Questions about eMDR?

- For technical questions about the HL7 or eSubmitter process, testing phases or for information on how to sign up for eMDR please contact the Information and Analysis Branch at: **emdr@fda.hhs.gov**

MDR Regulation Interpretation and Policy Questions:

Contact the Reporting Systems Monitoring Branch:

Phone: 301-796-6670
Email: **rsmb@fda.hhs.gov**

Mailing address:

Reporting Systems Monitoring Branch
FDA/CDRH/OSB/DPS
WO66, Room 3217
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Websites

- FDA Form 3500A and instructions:

www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

- Event Problem Code Website:

www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/ucm134751.htm

- Reports (redacted copies) are publically available at:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM